

(SPECIAL) 510(k) SUMMARY

JUL 25 2011

K103285

Submitter's Name and Address

(Device Sponsor and Manufacturer)

Dixtal Medical, Inc.

101 N. Plains Industrial Road

Bldg 2

Wallingford, CT 06492

Contact Person

Robert H. Schiffman, R.A.C. (EU)

Quality Assurance Manager

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Establishment Registration Number: 3006891479

Date the Summary was Prepared: September 24, 2010

Device/Trade Name/Common Name/Classification

Device Names (Proprietary/Trade Names): Dixtal DX-4100 Series Pulse Oximeter

Device Name (Common Name): Pulse Oximeter Monitor

Classification: Class II, 21CFR 870.2700/74DQA

Legally Marketed Predicate Devices

Legally marketed predicate devices to the Dixtal DX-4100 Series Pulse Oximeter:

- Philips Sure Signs Monitor, Model VM-1 (K082280)
- Philips picoSat II Pulse Oximeter engine (K081937)

Description of the Subject Device

The DX-4100 Series Pulse Oximeter Monitors is a modification to the Philips VM-1 (K081937) SpO₂/CO₂ Monitor. The Monitor uses the same picoSAT II^{plus} SpO₂ engine as the VM-1, the same power supply, battery and technically the same display (same resolution as used in the VM-1) and has the same intended use as the VM-1 (Pulse Oximetry only). The Monitors will use the Dixtal (FDA cleared: K100020) Pulse Oximetry DX Series SpO₂ Sensors. A second version of the DX-4100 Series Pulse Oximeter is equipped with the Philips receptacle thereby providing direct connection to the full line of sensors as indicated for the VM-1. Accuracy testing included with the sensor submission was performed with the Philips VM-1 monitor.

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Statement of Intended Use

The Dixtal DX-4100 Series Pulse Oximeter monitors are intended to provide continuous, non-invasive monitoring of functional arterial oxygen saturation (SpO_2) and pulse rate in neonatal, infant, pediatric and adult patients, in environments where pulse oximetry is indicated for use, when in the judgment of a licensed medical practitioner/physician pulse oximetry is required.

Environments of Use

The Dixtal DX-4100 Series Pulse Oximeter monitors is intended for use in healthcare environments including but not limited to, respiratory therapy, anesthesia, the intensive care unit (ICU), neonatal (NICU) and pediatric (PICU) intensive care units, hospital transport, and other environments where pulse oximetry is required.

Technological Characteristics

The Dixtal DX-4100 Series is a stand-alone Pulse Oximeter monitor. The device uses the same Pulse Oximetry engine as the predicate device (Philips Sure Signs Monitor, Model VM-1: K082280) as well as the same power supply and battery. The display is similar to the predicate device providing the same resolution as available with the VM-1. The Monitor has been designed to use the Dixtal (FDA cleared: K100020) Pulse Oximetry DX Series SpO_2 Sensors. A second version of the monitor will be equipped with the Philips receptacle and for use the Philips SpO_2 sensors.

Performance Data

Non-Clinical data

Biocompatibility, Cleaning and Disinfection

The DX-4100 Series Pulse Oximeter Monitors is a bedside monitor that is not intended for contact with patients and is only momentarily in contact with the clinical personnel. Therefore the monitor does not meet the criteria for Biocompatibility testing. The sensors intended for use with the monitor have been previously tested to assure biocompatibility for skin contact devices. SpO_2 sensors are labeled for reuse and can be cleaned to achieve a low level disinfection. The monitor can be wiped down for low level disinfection and cleaning.

Risks to Health

The Risk Assessment associated with the use of Pulse Oximeters and their sensors has been conducted and is documented and included in the Design Control Activities section of this submission. The Risk Assessment concluded the device is safe and effective for its intended use.

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Oxygen Saturation Sensors-Materials

Y-Sensor:

Sensor heads: silicone
Cable: silicone
Connector: PBT (thermoplastic polyester)

Finger Sensor:

Shell: Polycarbonate
Bladder: PVC
Foam spring: Silicone
Cable: Polyurethane
Connector: PBT (thermoplastic polyester)

Note - There is not any latex or natural rubber (which contains trace levels of latex), DEHP or Phthalates in these devices.

Performance Data

Clinical data

Controlled de-Sat (Accuracy) Testing was performed with the Dixtal DX Series sensors and the VM-1. This data was initially submitted in support of the recently cleared Premarket Submission for the Dixtal DX Series Sensors (K100020).

Literature review has been conducted, summarized and is presented in the design control section of this submission. The report includes Post Market data obtained from review of the FDA Maude database as well as from the scientific literature available from various publication sources.

Post Market Data specific (only) to the VM-1 (the picoSat II^{plus} engine is included in many of the Philips SureSigns VM and VS products) from April 2009 through June 2010 (>380 units distributed domestically) indicates less than 0.5% failure rate with no reportable events.

Conclusion: In compliance with Guidance documents, accepted Industry Standards and Design Control requirements, the documented results of verification and validation testing and hypoxia studies; establish the Dixtal DX Series 4100 Pulse Oximeter is substantially equivalent to the predicate devices.

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Pulse Oximetry-Background

Pulse Oximeters to which these sensors are connected measures oxygen saturation and pulse rate with sensors that contain red and infrared light sources. Since oxygen saturated blood absorbs different amounts of light at each wavelength (red and infrared) as compared with unsaturated blood, the amount of light absorbed at each wavelength by the blood in each pulse can be used to calculate oxygen saturation.

The light energy is beamed through a sample cell- a pulsating vascular bed, the patient's finger or toe for example. The remaining light energy not absorbed by the sample cell reaches a photodiode, on the opposing side of the sensor. The signal received by the photodiode is split into its red and infrared components, sampled, software filtered and displayed as a numerical value for oxygen saturation and as a waveform, the Plethysmogram.

Functional oxygen saturation is defined as: percentage saturation given by the oxyhaemoglobin concentration (cO_2Hb) divided by the sum of the oxyhaemoglobin concentration and the deoxyhaemoglobin concentration ($cHHb$)

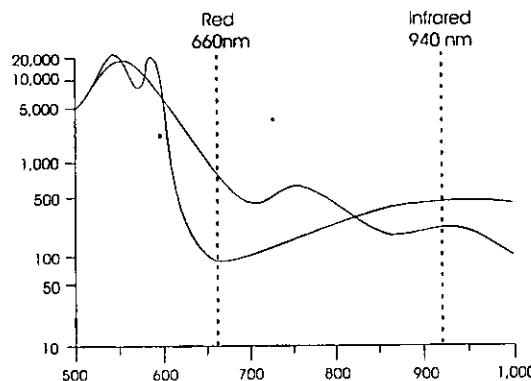
Fractional oxyhaemoglobin FO_2Hb : oxyhaemoglobin concentration cO_2Hb divided by the total haemoglobin concentration, c_{tHb} where

cO_2Hb is the concentration of oxyhaemoglobin;

c_{tHb} is the concentration of total haemoglobin.

This is sometimes reported as a percentage (multiplying the fraction by 100).

Functional saturation represents the amount of oxyhemoglobin as a percentage of the hemoglobin that can be oxygenated. Dysfunctional hemoglobin (COHb and METHb) are not included in the measurement of functional saturation.



Pulse Oximetry - Extinction Coefficients vs. wavelength (nm)

Pulse rate is calculated by measuring the time interval between the peaks of the infrared light waveform.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Mr. Robert H. Schiffman
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Dixtal Medical, Incorporated
101 North Plains Industrial Road
Wallingford, Connecticut 06492

JUL 25 2011

Re: K103285

Trade/Device Name: Dixtal DX-4100 Series Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: July 20, 2011
Received: July 21, 2011

Dear Mr. Schiffman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHO/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

Device Name: Dixtal DX-4100 Series Pulse Oximeter

Indications for use: The Dixtal DX-4100 Series Pulse Oximeter monitors are intended to provide continuous, non-invasive monitoring of functional arterial oxygen saturation (SpO2) and pulse rate in neonatal, infant, pediatric and adult patients, in environments where pulse oximetry is indicated for use, when in the judgment of a licensed medical practitioner/physician pulse oximetry is required.

Prescription Use ✓

AND/OR

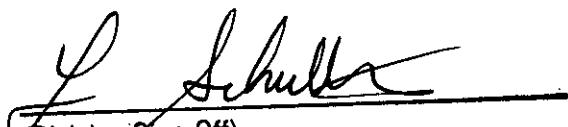
Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 103285